

10 JUN 2004

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Rec'd PCT/PTO 17 FEB 2005  
**PCT**

To:

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WRITTEN OPINION  
(PCT Rule 66)

Date of mailing  
(day/month/year) 14.06.2004

Applicant's or agent's file reference  
PB-46676

**REPLY DUE** within 3 month(s)  
from the above date of mailing

International application No.  
PCT/GB 03/03654

International filing date (day/month/year)  
20.08.2003

Priority date (day/month/year)  
21.08.2002

International Patent Classification (IPC) or both national classification and IPC  
A61K9/16, A61K9/16

Applicant  
PHOQUS PHARMACEUTICALS LIMITED et al.

1. This written opinion is the ~~first~~ <sup>second</sup> drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 21.12.2004

SEARCHED	PB	FILE NO.
INDEXED		46676
RECORDED	PD	

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**I. Basis of the opinion**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

1-25 as originally filed

**Claims, Numbers**

1-28 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

**WRITTEN OPINION**International application No. **PCT/GB 03/03654**

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Novelty (N)	Claims	1-4 (no); 5-28 (yes)
Inventive step (IS)	Claims	5-28 (yes)
Industrial applicability (IA)	Claims	1-28 (yes)

**2. Citations and explanations****see separate sheet****VI. Certain documents cited****1. Certain published documents (Rule 70.10)**

and / or

**2. Non-written disclosures (Rule 70.9)****see separate sheet**

Reference is made to the following document:

D1: EP 1 116 485

**Item V**

**1) Novelty**

The subject-matter of claims 1-4 is not new in the sense of Article 33(2) PCT in view of the prior art.

D1 already describes the use of an aqueous solution of sucrose and citric acid as granulation liquid (see example 1).

**2) Inventive step**

The subject-matter of claims 5-28 seems to be new and to involve an inventive step in the sense of Article 33(3) PCT in view of the prior art.

The problem to be solved was the stickiness during tableting of granules being made with an aqueous solution of citric acid as granulation liquid.

The solution provided is the addition of a water-soluble sugar like lactitol to the granulation liquid.

This problem did not occur in D1 since the granulate was used directly as such without any additional tableting step.

**3) Industrial applicability**

The subject-matter of claims 1-28 is industrially applicable in the sense of Article 33(4) PCT.

**Item VI**

The Applicant is informed that there exists an intermediate document which might become relevant in the European Phase of the application. The intermediate document is WO 03/072084 having a priority of 28.02.2002, a date of filing of 28.02.2003 and a publication date of 4.09.2003.